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AUG 29 2006

Page 3  
Dkt: USF-005

## AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/321,061

Amendment dated August 29, 2006

Reply to Office Action of March 29, 2006

**REMARKS/ARGUMENTS**

Applicants have carefully reviewed and considered the Office Action mailed on March 29, 2006, and the references cited therewith and provide the following remarks and arguments.

Claims 6-8 are amended, claims 2-5 are canceled; as a result, claims 1 and 6-8 are now pending in this application.

**Information Disclosure Statement**

Applicants submitted an Information Disclosure Statement and a 1449 Form on 10/27/05. Applicants gratefully acknowledge receipt of the signed copies of the 1449 Forms. Applicants also received a Notice of References cited by the Examiner.

**Affirmation of Election**

Restriction to one of the following claim sets was required:

- I. Claim 1 (protein purification);
- II. Claims 2 and 4 (an immunosuppressant protein); and
- III. Claims 3 and 5 (method of treating inflammation with the protein or source cells).

As provisionally elected on October 25, 2005, Applicants elected to prosecute the invention of Group I, claim 1.

The claims of the non-elected invention, claims 2-5, are hereby canceled. However, Applicants reserve the right to later file continuations or divisionals having claims directed to the non-elected inventions.

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Page 4  
Dkt: USP-005S112 Rejection of Claims 6-8

Claims 6-8 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 6 was said to be unclear for not stating if the added step was before step b). Claim 6 has been amended to state that the new step is between steps a) and b).

Claim 7 was found to be unclear as it added a step without clarifying the exact position. Claim 7 has been amended to clarify that position.

Claim 8 was found to be unclear because how the additional step would fit in the claim was unclear. Applicants also have amended this claim to clarify the order of the steps.

Therefore, Applicants believe that the claim amendments have rendered the Section 112 rejection moot and respectfully request withdrawal.

S102 Rejection of the Claims

Claims 1 and 6-8 were rejected under 35 USC § 102(b) as being anticipated by Gower *et al* (*J Neuroimmunol* 125 (March 2002) 103-113). The Office Action stated that Gower *et al* disclose a method for purifying an immunosuppressant protein (HISP) comprising obtaining supernatant from hNT cells, exposing the supernatant to preparative polyacrylamide gel electrophoresis, placing the active isoelectric fraction on a Blue Sepharose column, and collecting the free fraction containing the concentrated HISP. The Office Action further observed that there were additional steps of ultrafiltration and Sephacryl fractionation, and combining groups of five fractions and determining peak active fraction.

Applicants hereby submit Affidavits Under 37 CFR § 1.131 indicating that they invented the subject matter of this application before the cited article was published. Because the

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Serial Number: 10/621,061  
Amendment dated August 29, 2006  
Reply to Office Action of March 29, 2006

Page 5  
Dict: USF-005

Applicants invented the claimed invention before the publication of the cited article, this ground for rejection is moot. Applicants respectfully request that this rejection be withdrawn.

**Conclusion**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone the undersigned to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3956.

Respectfully submitted,

By their Representatives,

Date August 29, 2006  
The Luther Law Firm, PLC  
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By Barbara J. Luther  
Barbara J. Luther  
Reg. No. 33,954

Enclosure: Two copies of Affidavit Under 37 CFR § 1.131

**CERTIFICATE UNDER 37 CFR 1.61**: The undersigned hereby certifies that this correspondence is being transmitted by Facsimile to 1-571-273-8300 on this 29th day of August, 2006.

Barbara J. Luther  
Name

Barbara J. Luther  
Signature